



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,320	08/07/2001	Mark Huang	P893 US	3586

28390 7590 08/27/2003

MEDTRONIC AVE, INC.
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary	Application No.		Applicant(s)	
	09/924,320		HUANG, MARK	
	Examiner		Art Unit	
	Jessica R Baxter		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 6, 8, 9, 10, 12, 14, 16 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,066,156 to Yan.

Regarding claims 1, 2, 9, 10, 12, 14, 16 and 27, Yan discloses a balloon stent assembly comprising a balloon comprising an outer layer portion (adhesive 16), a stent (stent 18) disposed on the balloon covering at least 90 percent of the outer layer portion. Yan discloses that the outer layer portion flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature and retains the stent on the balloon during intravascular movement (Column 4 lines 3-15 and Column 7 lines 32-35).

Regarding claim 3, Yan discloses an inner layer (balloon 14).

Regarding claims 6 and 8, Yan discloses that the outer layer comprises a functionalized material that is not tacky below the predetermined temperature (Column 5 lines 45-56 and Column 7 lines 28-34).

3. Claims 1-3, 5, 9, 10, 12, 14, 16, 18, 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/33422 to Stoltze et al.

Regarding claims 1, 2, 3, 9, 10, 16, 18 and 27, Stoltze discloses a balloon stent assembly system comprising: a balloon (FIG. 5) including an outer layer portion; and a stent (stent 3) disposed on the balloon, the stent covering at least 55 percent of the outer layer

Art Unit: 3731

portion (FIG. 5); wherein the outer layer portion flows into gaps formed in the stent when the balloon stent assembly is heated (Page 14 line 14-Page 15 line 5) to a predetermined temperature, and retains the stent on the balloon during intravascular movement.

Regarding claims 6, 7 and 8, Stoltze discloses that the outer layer comprises a functionalized material selected from a group consisting of: polyethylene, ethylene-vinyl-acetate, acrylate, Bynel.RTM., and Plexar.RTM.(Page 16 lines 13-31).

Regarding claims 12 and 14, Stoltze discloses that the stent covers at least 90% of the outer layer portion (FIG. 5).

Regarding claims 22, 24 and 25, Stoltze discloses a method of retaining a stent on a balloon comprising: mounting the stent onto the balloon, the stent including gaps, the stent covering at least 55 percent of the balloon; sheathing the mounted stent and balloon (FIG. 7); heating the balloon; and flowing an outer layer of the balloon into the gaps formed in the stent while an inner layer of the balloon does not flow (Page 14 line 14-Page 15 line 5).

Regarding claim 23, Stoltze discloses that heating the balloon comprises elevating the balloon temperature to a temperature of about 50 to 70 degrees Celsius (Page 14 lines 19-23).

Regarding claim 26, Stoltze discloses pressurizing the balloon (page 14 lines 23-28).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

5. Claims 1-21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,327 to Green et al. in view of Yan '156.

Green discloses a balloon stent assembly comprising a balloon comprising an outer layer portion (second layer 140), a stent (stent 28) disposed on the balloon covering at least 90 percent of the outer layer portion (Table 1, Column 9). Green does not disclose that the outer layer portion flows into gaps formed into the stent when the balloon stent assembly is heated to a predetermined temperature. Yan teaches that a flowable adhesive is provided as an outer layer on a balloon in order to prevent stent movement or detachment (Column 3 lines 56-64), the transition from tacky to non-tacky of the outer layer is provided so that no adhesive residue is left on the stent after deployment (Column 4 lines 26-32), and the flowing in of the adhesive to the gaps formed in the stent provides a much smoother stent profile to be inserted into the vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of Green with the adhesive taught in Yan in order to prevent stent movement or detachment, prevent adhesive residue from being left on the stent after deployment, and to form a smoother profile to be inserted into a vessel.

Regarding claim 3, Green discloses an inner layer (inner layer 138).

Regarding claims 4 and 17, Green discloses that the outer layer and the inner layer comprise a co-extruded laminate (Column 9 lines 26-29).

Regarding claims 5 and 18, Green discloses that the outer layer comprises a tie layer material (Column 9 lines 34-43).

Regarding claims 6, 7 and 20, Green discloses that the outer layer comprises a functionalized material chosen from the group consisting of polyethylene, ethylene-vinyl-acetate, acrylate, Bynel, and Plexar (Column 8 lines 42-54).

Art Unit: 3731

Regarding claims 11, 13 and 15, Green discloses that at least 300-gram force of a stent retention force is provided (Column 8 lines 55-65).

Regarding claim 19, Green discloses that the outer layer comprises a first material and the inner layer comprises a second material different from the first material (Column 8 lines 18-54).

Response to Arguments

6. Applicant's arguments filed June 4, 2003 have been fully considered but they are not persuasive.

Applicant argues that the adhesive material of Yan '076 is not heated. The fact that it is not specifically heated is irrelevant. Yan discloses that the adhesive is heat sensitive and can be heated. Therefore the rejection is proper.

Applicant argues that the temperature range is different in Yan '076 than as claimed, i.e. that it works in the opposite manner in terms of when it is tacky and when it is non-tacky. However, Yan discloses that the temperature ranges can be changed and the temperature range of tacky temperatures can be reverse than that of the embodiment discussed in the disclosure (Column 7 lines 39-42).

Applicant argues that the adhesive of Yan '076 does not flow into the gaps. The adhesive in Figure 3 appears to flow into the gaps.

In addition, the arguments appear to be based on a method of mounting a stent on a balloon. Claims 1-21 and 27 are apparatus claims, not method claims. The structural limitations, as claimed, are met by Yan' 076 and Green '327 in view of Yan '076.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3731

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


Jrb

August 21, 2003



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700